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ADSCaN: A Randomised Phase II study of Accelerated, Dose escalated, Sequential Chemo-radiotherapy in Non-Small Cell Lung Cancer (NSCLC)

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Introduction: Lung cancer is the most common cause of cancer mortality in the UK, and NSCLC accounts for approximately 85% of all lung cancers. Most patients present with inoperable disease therefore radiotherapy plays a major role in treatment. However, the majority of patients are not suitable for the gold standard treatment (concurrent chemo-radiotherapy) due to performance status and comorbidities. Novel strategies integrating radiotherapy advances and radiobiological knowledge need to be evaluated in patients treated with sequential chemo-radiotherapy. Four separate dose escalation accelerated radiotherapy schedules have been completed in UK (CHART-ED, IDEAL-CRT, I-START and Isotoxic IMRT). ADSCaN will compare these schedules with a UK standard sequential chemo-radiotherapy schedule. A combined randomized phase II screening/‘pick the winner’ approach will identify the best schedule to take into a randomised Phase III study against conventionally fractionated radiotherapy.

Methods: Suitable patients will have histologically/cytologically confirmed, stage III NSCLC and are able to undergo chemoradiotherapy treatment. The study will recruit 360 patients; 130 on the standard arm and 60 on each experimental arm. Patients will complete 2–4 cycles of a platinum based chemotherapy before being randomised on study to one of the radiotherapy schedules. There would be logistic and capacity problems making it impractical for most sites to open all experimental trial arms. The novel trial design allows centres to select upfront which of the experimental arms they are able to participate in. All centres will have the standard arm available.

Conclusion: The study is in set up, with an anticipated start date of November 2016. Recruitment will last 3 years 8 months with a subsequent 12 months follow up period.

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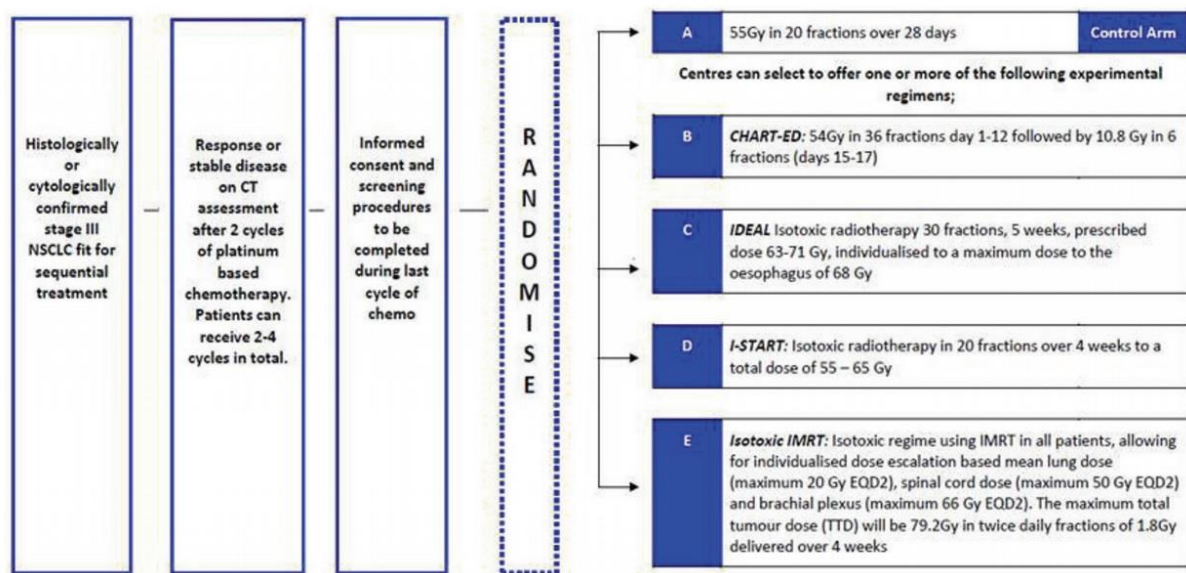


Figure 1- ADSCaN trial schema